PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPEAL BRIEF FILED UNDER 37 CFR 1.192

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

RE: Patent Application No.	10/762,300
Filing Date:	01/23/2004
Inventor:	WANG et al.
Title:	POWDER FORMATION BY ATMOSPHERIC SPRAY-FREEZE DRYING
Group Art Unit:	3749
Examiner:	GRAVINI, Stephen Michael
Attorney Docket No.	364-2US

INDEX

1. INTRODUCTION

This is an appeal to the Board of Appeals and Interferences from the office action dated January 11, 2005. In the detailed action, the examiner rejected Claims 1, 2 and 8 under 35 U.S.C. 102(b) as being anticipated by a reference cited by the applicant, "Spray freeze-drying - the process of choice for low water soluble drugs?" by H. Leuenberger (LEUENBERGER). The examiner rejected Claims 10-14 and 26-28 under 35 U.S.C. 102(b) as being anticipated by US 6,284,282 to MAA et al. (MAA). The examiner rejected Claims 15-20 under 35 U.S.C. 102(b) as being anticipated by US 5,900,384 to Soltani Ahmedi et al. (SOLTANI). The examiner rejected Claims 4-7 and 9 under 35 U.S.C. 103(a) as being unpatentable over LEUENBERGER in view of SOLTANI. The examiner rejected Claims 21-25 under 35 U.S.C 103(a) as being unpatentable over LEUENBERGER in view of MAA. The examiner erred in all of these rejections.

2. REAL PARTY IN INTEREST

The inventors are the real party in interest. The inventors are researchers at the University of Alberta, Canada. The University of Alberta has a partial share in the invention according to the inventors' employment terms with the University of Alberta.

3. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

4. STATUS OF CLAIMS

Claims 1, 2, and 4-28 are pending and have all been rejected by the examiner. It is this rejection that is being appealed.

5. STATUS OF AMENDMENTS

There are no amendments pending on this appeal.

6. SUMMARY OF INVENTION

All paragraph numbers are those of the application as filed. There are three independent claims, namely claims 1, 10 and 15. The following summarizes the content of the three independent claims and the claims dependent on them.

As set out in claim 1, the invention is directed to a method of creating a powder, comprising the steps of:

spraying a carrier liquid containing a powder forming ingredient to form a flow of liquid droplets (para. 14, para. 19);

entraining the flow of liquid droplets within a concurrent flow of coolant for sufficient time to freeze the liquid droplets into frozen particles (para. 14, para. 19); and

drying the frozen particles to form a dry powder (para. 14, para. 19).

The powder forming ingredient is suspended or dissolved in the carrier liquid (claim 2, para. 19).

The concurrent flow of coolant is sprayed from a ring nozzle (claim 4, para. 16, para. 17).

The liquid droplets is injected into a chamber and entrained by flowing coolant injected through porous walls of the chamber (claim 5, para. 15).

The porous walls of the chamber comprises side walls, and the carrier liquid is sprayed from a first end of the chamber (claim 24, para. 15, para. 20).

The frozen particles is collected on a filter at an end of the chamber opposed to the first end, and dried on the filter (claim 25, para. 15, para. 20).

The frozen particles is collected on a filter (claim 6, para. 19, para. 21, para. 22).

The flow of coolant has a temperature within a first temperature range during freezing of liquid particles and a temperature warmer than the first temperature range during drying of the frozen particles (claim 8, para. 24).

The carrier liquid contains more than one powder forming ingredient (claim 9, para. 13).

The coolant is a gas (claim 21, para. 18).

The coolant is a gas formed by vaporization of cold liquid (claim 22, para. 18).

The cold liquid is liquid nitrogen (claim 23, para. 18).

As set out in Claim 10, another embodiment of the invention is directed to a method of creating a powder within a chamber, the method comprising the steps of:

providing a flow of liquid droplets containing a powder forming ingredient to form a flow of liquid droplets (para. 14, para. 18, para. 19);

treating the liquid droplets with a flow of coolant inside the chamber to freeze the liquid droplets to form frozen particles prior to deposition (para. 19);

depositing the frozen particles on a collector (para. 19); and

after deposition of the frozen particles, drying the deposited frozen particles, to form a dry powder (para. 21).

The flow of coolant is concurrent with the flow of liquid droplets (claim 11, para. 18, para. 19, para. 20).

The flow of coolant for drying frozen particles is in co-direction with gravity. (claim 12, para. 20, para. 24).

The flow of coolant prevents adherence of liquid droplets to walls of the chamber (claim 13, para. 20).

The flow of liquid droplets contains more than one powder forming ingredient (claim 14, para. 13).

The coolant is a gas (claim 26, para. 18).

The coolant is a gas formed by vaporization of cold liquid (claim 27, para. 18).

The cold liquid is liquid nitrogen (claim 28, para. 18).

As set out in Claim 15, another embodiment of the invention is directed to an apparatus for atmospheric spray-freeze drying of an ingredient carrying liquid to form a powder, the apparatus comprising:

a chamber having an atomizer at one end of the chamber, the atomizer being connected to a source of the ingredient carrier liquid to produce a flow of liquid droplets (para. 15, para. 16, para. 17);

an injection system for providing a flow of coolant that entrains liquid droplets sprayed by the atomizer (para. 18);

a source of coolant for the injection system (para. 18); and

a collector spaced from the atomizer sufficiently that liquid droplets atomized by the atomizer are frozen by the flow of coolant before contact with the collector (para. 19).

The injection system and atomizer is oriented to provide concurrent flows of coolant and liquid droplets (claim 16, para. 24).

The injection system comprises a ring nozzle surrounding he atomizer (claim 17, para. 16, para. 17).

The injection system is arranged around a porous wall defining a flow chamber through which the flow of coolant passes (claim 18, para. 15, para. 20).

The collector is a filter at an exit from the chamber (claim 19, para. 15, para. 16, para. 17, para. 19).

The atomizer and collector is at opposed ends of the chamber (claim 20, para.15, para. 16, para. 17).

7. GROUPING OF CLAIMS

Claims 1, 2, 8, and 21 are argued as a group.

Claims 10 through 14 are argued separately.

Claims 26 to 28 are argued as a group.

Claims 15 through 20 are argued separately.

Claim 9 is argued with Claims 4 to 7 as a group, but Claims 4 to 7 are also argued separately.

Claim 21 is argued separately.

Claims 22 and 23 are argued as a group.

Claims 24 and 25 are argued separately.

The rejections will be argued in this order.

8. THE REFERENCES

The following references are relied on by the examiner:

H. Leuenberger, "Spray freeze-drying - the process of choice for low water soluble drugs?", Journal of nanoparticle research, vol. 4, 2002, pp. 111-119. (LEUENBERGER)

US 5,900,384	May 4, 1999	Soltani-Ahmadi et al. (SOLTANI)
US 6,284,282	September 4, 2001	MAA et al. (MAA)

9. BRIEF DESCRIPTION OF THE REFERENCES

LEUENBERGER discloses a method of atmospheric spray freeze drying of a carrier liquid to form a dry powder. As shown in Fig. 4, page 116 of LEUENBERGER, and particularly described beginning in the right hand column of page 115, the carrier liquid is sprayed from a spray nozzle 2 downward against a flow of coolant (cold air) that emanates upward from the base of the chamber. Thus, the flow of coolant is countercurrent to the sprayed carrier liquid. In theory, the frozen droplets thus produced are blown towards a filter 5 where they dry in the cold dessicated air stream. Temperature and humidity of the air stream are regulated by the apparatus on the right side of the figure.

MAA describes a spray freeze drying process for the preparation of aerosol powders. As

shown in Fig. 1, carrier liquid is injected through a nozzle that atomizes the carrier fluid as it passes into a flask containing liquid nitrogen. The atomized carrier fluid is frozen into droplets upon contact with the liquid nitrogen (col. 11, lines 47-66, col. 16, lines 6-20). After freezing of the droplets, the droplets are dried. This process, described generally at col. 11, line 65 to col. 12, line 17, but more particularly at col. 16, lines 22-30, requires removal of the entire contents of the flask to a metal tray (col. 16, line 22) for treatment in a vacuum drying chamber.

SOLTANI describes a spray drying process for the product of fine particle size metal catalysts. SOLTANI describes a spray drying process with reference to Fig. 1. Fig. 1 of SOLTANI shows a spray drying process in which a carrier liquid (slurry) is atomized through a nozzle 15 and heated by a flow of air supplied through drying gas inlets 18 and heater 19. The droplets sprayed from the nozzle 15 dry in the chamber 7 and are separated from the drying gas in cyclone 21 for collection in container 23. Solvent vapours are recovered by cold traps 27 and 29. SOLTANIi refers to a freeze drying process as an alternative method for the preparation of the catalysts (col. 8, lines 48-63) but refers to the equipment only generally (col. 8, lines 59-61) and does not provide an illustrative embodiment of a freeze drying process.

10. THE REJECTION

Claims 1, 2 and 8 stand rejected under 35 U.S.C. 102(b) as being anticipated by a reference cited by the applicant, "Spray freeze-drying - the process of choice for low water soluble drugs?" by H. Leuenberger (LEUENBERGER). Claims 10-14 and 26-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by US 6,284,282 to MAA et al. (MAA). Claims 15-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by US 5,900,384 to Soltani Ahmedi et al. (SOLTANI). Claims 4-7 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LEUENBERGER in view of SOLTANI. Claims 21-25 stand rejected under 35 U.S.C 103(a) as being unpatentable over LEUENBERGER in view of MAA.

11. ARGUMENT

I. Introduction

The applicant submits that the examiner's rejection of Claims 1, 2, 8, 10-20, and 26-28 under 35 U.S.C. 102(b) is improper because the various references cited against the claims do not teach each and every element as set forth in the claim, either expressly or inherently. The examiner has failed to understand the cited references.

The rejection of Claims 4-7, 9, and 21-25 under 35 U.S.C. 103 (a) is improper because the examiner did not correctly determine the scope and contents of the prior art, did not correctly ascertain the differences between the prior art and the claims in issue, and failed to identify any motivation or suggestion in the teachings to combine them. Therefore, the applicant submits that the examiner's has failed to make out a *prima facie* case of obviousness.

II. Summary of the Law

Under 35 U.S.C. 102(b), "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The applicants submit that the examiner has misunderstood the references and what is claimed by the applicants, and therefore attributed to the references features they lack. The examiner's rejection of the claims based on anticipation must be reversed.

Under 35 U.S.C. § 103(a), a rejection of the claims generally must meet four key elements as set out by the Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), and summarized in the *Manual of Patent Examining Procedure (MPEP) Edition 8 (E8), August, 2001, Latest Revision May 2004*, s. 2141. These elements are as follows:

> (A) Determining the scope and contents of the prior art;
> (B) Ascertaining the differences between the prior art and the claims in issue;
> (C) Resolving the level of ordinary skill in the pertinent art; and
> (D) Evaluating evidence of secondary considerations.

Applicant submits that the examiner has failed to determine correctly the scope and contents of the prior art and also to assess properly the differences between the references and the claimed invention, choosing to ignore the content of the teachings where they teach away from each other and from the applicant's invention.

Applicant also submits that the examiner failed to identify any motivation or suggestion in the teachings to combine them. As summarized in MPEP, s. 2143.01:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The following points are also observed in MPEP, s. 2143.01:

- The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).
- The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

The examiner has made arguments which ignore these points. As a result, the examiner has failed to establish a *prima facie* case of obviousness. Because of the examiner's failure, the rejection of the claims based on obviousness must be reversed.

III. Claims 1, 2 and 8 stand rejected under 35 U.S.C. 102(b) as being anticipated by LEUENBERGER

The examiner has misunderstood LEUENBERGER and arrived at a faulty conclusion of anticipation of Claims1, 2, and 8, since LEUENBERGER does not teach each and every element of the claims.

The examiner cites LEUENBERGER as disclosing entraining the flow of liquid droplets within a concurrent flow of coolant and cites page 115, right column, of the reference. This is not true. LEUENBERGER discloses countercurrent flow, see Fig. 4 and the discussion of Fig. 4 at page 115. In LEUENBERGER, there is no concurrent flow, there is no entrainment of liquid droplets and there is no entrainment of the flow of liquid droplets within a flow of coolant. As stated in LEUENBERGER, "solutions are sprayed against a stream of cold air". This is not a concurrent flow. LEUENBERGER emphasizes the countercurrent flow at page 118, second bullet: "The droplets are immediately frozen in a counter stream of air with a temperature of -60C". The spray from element 2 in Fig. 4 evidently sprays outward against a flow of air from a simple opening. These flows will evidently mix together and do not provide entrainment of one flow within the other. Nothing in LEUENBERGER teaches or suggests concurrent flow or entrainment.

Thus claim 1, and consequently claims 2, 8 and 21, are patentable over LEUENBERGER.

IV. Claims 10-14 and 26-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by MAA

The examiner has misunderstood MAA and arrived at a faulty conclusion that MAA anticipates Claims 10-14 and 26-28, since MAA fails to teach each and every element of the

claims.

For Claim 10, the examiner cites MAA as disclosing all the elements of the claim. However, MAA fails to disclose a process that occurs within a chamber as claimed in Claim 10. In MAA, freezing of particles takes place in a flask (Fig. 1). However, drying takes place after emptying the contents of the flask onto a tray (col. 16, line 22). MAA fails to anticipate Claim 10.

For Claim 11, MAA fails to disclose flow of coolant concurrent with flow of liquid droplets. The examiner cites col. 18, lines 29-36 as showing concurrent flow of coolant but this section of MAA refers to powder measurements and is irrelevant. In MAA, the coolant is liquid nitrogen that, in some embodiments, may be stirred with a stirring bar (col. 11, lines 56-58). The stirring bar (Fig. 1) is manipulated by a magnetic stirrer. It is not disclosed how the magnetic stirrer stirs the liquid. Presumably the stirring would be a rotational movement, which would provide tangential flow of coolant and not countercurrent flow. MAA fails to anticipate Claim 11.

For Claim 12, MAA fails to disclose flow of coolant in co-direction with gravity. The examiner cites Fig. 1 as showing flow of coolant in co-direction with gravity but this is not correct. MAA describes stirring of coolant, but does not describe how the flow occurs. MAA therefore fails to anticipate Claim 12.

For Claims 13 and 14, the discussion at col. 27, line 6-22 in MAA, cited by the examiner for teaching chamber wall adherence prevention and more than one powder forming ingredient, actually discusses a completely separate step of later adding particles formed by MAA's process to a carrier. It has nothing to do with the formation of the powder itself. Also, there is nothing in this section to discuss more than one powder forming ingredient. MAA fails to anticipate Claims 13 and 14.

For Claims 26 to 28, the examiner cites MAA, col. 16, lines 7-30 as teaching flow of gas formed by the vaporization of cold liquid nitrogen. However, in MAA, col. 16, lines 7-30, there is no flow of gas formed by the vaporization of cold liquid nitrogen as cited by the examiner. There is no mention of nitrogen gas, and no flow either. Nor is there mention of nitrogen gas

causing freezing of anything. At col. 16, lines 19-20, MAA states: "Sprayed droplets froze upon contacting liquid N2." The material is removed from the flask and placed in a lyophilizer for a drying step. Hence, MAA does not use gas for cooling (Claim 26). MAA does not use gas formed by vaporization of a liquid (Claim 27). And MAA does not use liquid nitrogen as a source of coolant gas (Claim 28). MAA does not anticipate Claims 26 to 28.

Hence, each of claims 10-14 and 26-28 are patentable over MAA, because MAA does not describe exactly the same thing as claimed and cannot anticipate the claims.

V. Claims 15-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by SOLTANI

The examiner has misunderstood SOLTANI and arrived at an erroneous conclusion that SOLTANI anticipates Claims 15-20.

For Claim 15, the examiner cites SOLTANI as disclosing an injection system 15 for providing a flow of coolant that entrains liquid droplets sprayed by the atomizer. The examiner in his response to applicants' argument specifically cites the first line of col. 8 of that reference as teaching a coolant. But all that line states is that the fluid passing through line 9, which is used for liquid droplets feeding, may be heated or cooled. The fluid passing through line 9 is what the examiner recites as the supply of liquid droplets. So, the supply of liquid droplets according to SOLTANI may be heated or cooled. However, the claim recites both an atomizer to produce a flow of liquid droplets and an injection system for providing a flow of coolant that entrains liquid droplets sprayed by the atomizer. The fluid in line 9 cannot be both a coolant and the liquid droplets that are entrained by the flow of coolant. Either it is the liquid droplets or it is the coolant, but it cannot be both.

Put another way, the examiner misconstrues the nozzle 15 of the atomizer 17 (col. 8, line 6) of SOLTANI as a separate injection system from the atomizer. However, the nozzle 15 is just the outlet of the atomizer 17, it is not a separate device. Further, if the coolant were supplied through the atomizer, it would freeze the atomizer, so there cannot be coolant supplied through the atomizer.

The examiner seems to consider that SOLTANI provides for freezing of liquid droplets

(page 4 of the official action, line 9), but a careful reading of SOLTANI shows that Fig. 1 and the corresponding description is about spray drying with heat from heater 19. A separate freeze drying process is mentioned but not described in SOLTANI (col. 8, lines 48-63). The examiner appears to confuse the two different approaches referred to by SOLTANI.

The confusion of the examiner in relation to SOLTANI is emphasized in that the examiner refers to a source of coolant 28 for the nozzle system, but the coolant in refrigerator 28 of Fig. 1 of SOLTANI is a cold trap for recovering solvent vapours. The coolant from refrigerator 28 is not supplied to line 9 at all as suggested by the examiner.

Hence, claims 15 and 20 are patentable over SOLTANI, since SOLTANI does not teach each and every element of the claims.

For Claim 16, the examiner cites SOLTANI for the claimed concurrent flows of coolant and liquid droplets, but as mentioned above in relation to Claim 15, SOLTANI's Fig. 1 is about a heated drying process and not a cooling process. There is no concurrent flow of coolant. SOLTANI does not anticipate Claim 16.

For Claim 17, the examiner states that SOLTANI anticipates the claimed ring nozzle by its spinning disc atomizer because both are circularly oriented. By this logic, a dog is a cat because both have four legs. It's plainly wrong. A spinning disc from which liquid droplets spin off the outer edge of the disc is quite different from a ring with nozzles spaced around the ring to direct flow to form a cylindrical curtain of liquid. SOLTANI does not anticipate Claim 17.

For Claim 18, the examiner states that SOLTANI anticipates an injection system arranged around a porous wall defining a flow chamber. The walls defining the flow part of the chamber 7 of Fig. 1 of SOLTANI are solid except for the exit, and there is no injection system arranged around them. SOLTANI does not anticipate Claim 18.

For Claim 19, it is clear that Claim 19 recites that the collector is filter. The examiner cites a filter 25 in the solvent recovery section of Fig. 1 as the claimed filter. However, the powder droplet collector of SOLTANI is a centrifuge 21 and container 23. The filter 25 does not collect frozen droplets. The filter 25 is for filtering vapor to ensure a clean gas passes to the aspirator pump (a standard procedure). SOLTANI does not anticipate Claim 19.

Hence, SOLTANI does not describe exactly the same thing as and cannot anticipate claims 15-20.

VI. Claims 4-7 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LEUENBERGER in view of SOLTANI

The examiner has failed to properly determine the scope and contents of the prior art, and failed to correctly determine the differences between the prior art and the claims. The examiner has also not demonstrated any motivation or suggestion in the prior art to combine the references. As such, the examiner has not made out a prima facie case of obviousness, and the rejection of Claim 4 to 7 and 9 should be reversed.

For each of claims 4-7 and 9, the citation of LEUENBERGER against claim 1 is wrong for reasons given above, and SOLTANI's Fig. 1 is irrelevant to a freezing process. Fig. 1 of SOLTANI discloses a system that heats to dry, completely contrary to the system of LEUENBERGER, which freezes. The two references are therefore individually irrelevant and incompatible teachings, and cannot be combined. Even supposing they were combined, all that would happen is that LEUENBERGER's disclosure of cooling would be replaced by heating, which would contradict the claimed freezing of liquid droplets. These objections are sufficient to overcome this rejection, but also the following arguments apply.

For Claim 4, SOLTANI discloses a spinning disc atomizer. There is no ring nozzle in SOLTANI that supplies coolant. Hence, combination of the references does not yield the invention.

For Claim 5, the examiner cites SOLTANI in relation to claim 5 as disclosing porous walls. However, the inlets 18 in the walls of the chamber of SOLTANI provide heating fluid, not coolant. Hence, combination of the references does not yield the invention.

For Claim 6, the filter of SOLTANI is used in a vapour recovery system and is not a collector for frozen droplets. Hence, combination of the references does not yield the invention.

For Claim 7, SOLTANI dries in the chamber 7 and collects in container 23. Nothing in SOLTANI discloses or suggests frozen droplet drying on a filter. Hence, combination of the references does not yield the invention.

Because there is no motivation or suggestion to combine the references, and because they cannot be combined into anything that yields the invention, each of claims 4-7 and 9 are patentable over LEUENBERGER in view of SOLTANI.

VII. Claims 21-25 stand rejected under 35 U.S.C 103(a) as being unpatentable over LEUENBERGER in view of MAA

The examiner has failed to properly determine the scope and contents of the prior art, and failed to correctly determine the differences between the prior art and the claims. The examiner has also not demonstrated any motivation or suggestion in the prior art to combine the references. As such, the examiner has not made out a prima facie case of obviousness, and the rejection of Claims 21 to 25 should be reversed.

Both LEUENBERGER and MAA are irrelevant for reasons already given.

Furthermore, for Claim 21, LEUENBERGER discloses use of a gas for cooling, so the examiner is wrong to cite MAA, which discloses liquid nitrogen for cooling. The patentability of Claim 21 is dependent on the patentability of claim 1, which is patentable for reasons already given. The references cannot be combined, and therefore, Claim 21 is not obvious.

For Claims 22 and 23, in relation to claims 21-25, the examiner cites MAA as disclosing vaporization of liquid nitrogen at col. 8, lines 1-54, but this is plainly wrong since that section of MAA deals only with addition of excipients. MAA uses liquid nitrogen to freeze droplets. LEUENBERGER uses cold air. It is not easy to see what the combination of LEUENBERGER and MAA would be. At best, perhaps placing a bath of liquid nitrogen in the base of the chamber of Fig. 1 of LEUENBERGER. Nothing in either reference suggests using liquid nitrogen as a source of cold nitrogen gas. Hence, the combination of the references does not yield the invention.

For Claim 24, the examiner also cites MAA as disclosing porous side walls in Fig. 1.

This is also wrong, since MAA discloses a two-neck round-bottomed flask submerged in a container also containing liquid N2 (col. 16, lines 13-14). Nothing in MAA suggests that the flask has porous walls. Hence, the combination of the references does not yield the invention.

For Claim 25, MAA does not disclose a filter in the chamber. The examiner cites col. 15, line 54 to col. 16, line 6 as disclosing a filter, but this filter is used to filter air entering the spray nozzle, and does not act as a filter for frozen droplets. Hence, MAA fails to teach anything relevant about filters in the chamber. Hence, the combination of the references does not yield the invention.

Because there is no motivation or suggestion to combine the references, and because they cannot be combined into anything that yields the invention, each of claims 21-25 are patentable over LEUENBERGER in view of MAA.

12. CONCLUSION

The examiner has misunderstood the references, and therefore erroneously rejected all the claims, either by suggesting that some of the claims are anticipated by references that do not teach each and every element of the claims, or by failing to establish a *prima facie* case of obviousness. It is therefore submitted that the claims on appeal are in condition for allowance, and that the rejection of all the claims, either based on anticipation or obviousness, should be reversed.

Respectfully submitted

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APPENDIX TO APPEAL BRIEF FILED UNDER 37 CFR 1.192
IN APPLICATION SN 10/762,300 SHOWING CLAIMS ON APPEAL

1. A method of creating a powder, comprising the steps of:

spraying a carrier liquid containing a powder forming ingredient to form a flow of liquid droplets;

entraining the flow of liquid droplets within a concurrent flow of coolant for sufficient time to freeze the liquid droplets into frozen particles; and

drying the frozen particles to form a dry powder.

2. The method of claim 1 in which the powder forming ingredient is suspended or dissolved in the carrier liquid.

3. Cancelled.

4. The method of claim 1 in which the concurrent flow of coolant is sprayed from a ring nozzle.

5. The method of claim 1 in which the flow of liquid droplets is injected into a chamber and entrained by flowing coolant injected through porous walls of the chamber.

6. The method of claim 1 in which the frozen particles are collected on a filter.

7. The method of claim 6 in which the frozen particles are substantially dried after being collected on the filter.

8. The method of claim 1 in which the flow of coolant has a temperature within a first temperature range during freezing of the liquid particles and a temperature warmer than the first

temperature range during drying of the frozen particles.

9. The method of claim 1 in which the carrier liquid contains more than one powder forming ingredient.

10. A method of creating a powder within a chamber, the method comprising the steps of:

providing a flow of liquid droplets containing a powder forming ingredient to form a flow of liquid droplets;

treating the liquid droplets with a flow of coolant inside the chamber to freeze the liquid droplets to form frozen particles prior to deposition;

depositing the frozen particles on a collector; and

after deposition of the frozen particles, drying the deposited frozen particles , to form a dry powder.

11. The method of claim 10 in which flow of coolant is concurrent with the flow of liquid droplets.

12. The method of claim 10 in which flow of coolant for drying frozen particles is in co-direction with gravity.

13 The method of claim 10 in which the flow of coolant prevents adherence of liquid droplets to walls of the chamber.

14. The method of claim 10 in which the flow of liquid droplets contains more than one powder forming ingredient.

15. Apparatus for atmospheric spray freeze drying of an ingredient carrying liquid to form a

powder, the apparatus comprising:

a chamber having an atomizer at one end of the chamber, the atomizer being connected to a source of the ingredient carrier liquid to produce a flow of liquid droplets;

an injection system for providing a flow of coolant that entrains liquid droplets sprayed by the atomizer;

a source of coolant for the injection system; and

a collector spaced from the atomizer sufficiently that liquid droplets atomized by the atomizer are frozen by the flow of coolant before contact with the collector.

16. The apparatus of claim 15 in which the injection system and atomizer are oriented to provide concurrent flows of coolant and liquid droplets.

17. The apparatus of claim 16 in which the injection system comprises a ring nozzle surrounding the atomizer.

18. The apparatus of claim 17 in which the injection system is arranged around a porous wall defining a flow chamber through which the flow of coolant passes.

19. The apparatus of claim 15 in which the collector is a filter at an exit from the chamber.

20. The apparatus of claim 19 in which the atomizer and collector are at opposed ends of the chamber.

21. The method of claim 1 in which the coolant is a gas.

22. The method of claim 21 in which the coolant is a gas formed by vaporization of a cold liquid.

23. The method of claim 22 in which the cold liquid is liquid nitrogen.

24. The method of claim 5 in which the porous walls of the chamber comprise side walls, and the carrier liquid is sprayed from a first end of the chamber.

25. The method of claim 24 in which the frozen particles are collected on a filter at an end of the chamber opposed to the first end, and dried on the filter.

26. The method of claim 10 in which the coolant is a gas.

27. The method of claim 26 in which the coolant is a gas formed by vaporization of a cold liquid.

28. The method of claim 27 in which the cold liquid is liquid nitrogen.